REMARKS

This amendment responds to the office action mailed on February 09, 2007. Claim 1 is amended. Reconsideration is respectfully requested in light of these amendments and the following remarks.

Claims 1-2, 4-7, 9-22 and 25-34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Song (U.S. 5,949,999) in view of Selkirk (U.S. Patent Application Pub. 2002/0087673) in view of Briegs (U.S. 7,054,823) and further in view of Hartel (U.S. Patent Application Pub. 2003/0028549). The patent owner respectfully disagrees with these rejections. Nonetheless, to expedite prosecution, independent claim 1 has been amended to further distinguish over the cited references.

Claim 1 has been amended to specify that the links contained in the first metadata structure include metadata that indicates how the collected data interrelates with the subsequent biomedical development phase. As explained in the specification, the inclusion of this interrelationship data provides traceability among the different phases of a biomedical development project. In addition, the inclusion of metadata describing the interrelationship allows analysts to exploit the interrelationships. (See, Specification, pages 11 and 14.)

Among other distinctions, none of the cited references, either alone or in combination, provide a metadata structure that includes links to another metadata structure associated with a subsequent biomedical development phase so that an audit trail may be generated, in which the links include metadata that indicates how the collected data interrelates with the subsequent biomedical development phase, as recited in amended claim 1. More specifically, the office action cites to paragraph 0024 of the Selkirk reference as corresponding to the claim 1 limitation "wherein at least a portion of the first metadata structure contains links to another metadata

structure associated with the subsequent biomedical development phase." However, paragraph 0024 of the Selkirk reference merely teaches that metadata may include "pointers to related metadata units." The Selkirk reference clearly does not suggest the inclusion of metadata that indicates how the data interrelates with data in a subsequent development phase. For at least this reason, the patent owner submits that claim 1, as amended, is patentably distinct from the cited references.

Moreover, the patent owner submits that independent claim 1 is patentably distinct from the cited references, even absent the amendment, because none of the cited references relate to a computer-implemented system that integrates data from a plurality of biomedical development phases. The office action apparently gives little weight to the elements of claim 1 that specify how the claimed system is utilized within the phases of a biomedical development project, because the cited references clearly make no reference to anything even remotely similar to biomedical development or the data retrieval problems associated therewith.[1] The patent owner submits that it is improper to divorce these elements from the claim.

As previously explained, the claimed system provides a substantial benefit to the biomedical research industry because the non-standardized data technology systems that were typically employed in the biomedical industry were insufficient to provide the necessary information at the numerous stages of a biomedical development project, including the FDA approval stage. As a demonstration of this void in the prior art, several customer testimonials are attached as Exhibits A-D relating to the SAS Drug Development software package, which is sold by the Assignee and employs the invention set forth in pending claim 1. As shown by these

[1] As explained in a previous office action response, the mere mention of the FDA at column 2 of the Song reference as a regulatory agency that may audit the development of safety-critical software systems clearly does not justify the office action's conclusion that the Song reference somehow discloses software for collecting data from phases of a biomedical development project.

testimonials, the use of the claimed computer-implemented system to provide traceability between the stages of the biomedical development project fills a long-felt and previously unresolved need in the biomedical industry. It is therefore improper for the Office Action to effectively read elements out of the claims by concluding that a person skilled in the art would find it obvious to extend the systems described in the combination of the four cited references to provide a system for integrating data from biomedical development phases. Indeed, the fact that the Office Action requires the combination of four very different references, none having anything at all to do with biomedical development, evidences that persons skilled in the art would not find claim 1 obvious.

For at least these reasons, the patent owner submits that independent claim 1 is patentable over the cited references. Claims 2, 4-7, 9-22 and 25-34 depend from claim 1 and are thus also patentable.

Respectfully submitted,

JONES DAY

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Exhibit A

NEOPHARM TAKES DRUG CANDIDATES TO THE NEXT LEVEL

SAS® Drug Development simplifies data management, data analysis and regulatory submissions

Industry

Pharmaceutical

Business Issue

Supply clinical study data to a wide range of users.

Solution

SAS® Drug Development.

Benefits

SAS® provides a comprehensive solution for managing, analyzing and reporting clinical study data in a validated environment.

In its quest to discover new treatments for lethal, rapidly progressing forms of cancer, biopharmaceutical company NeoPharm has developed an impressive portfolio of cancer-fighting drugs. Currently, four of NeoPharm's drug compounds are in clinical trials – where physicians are studying these drug candidates' abilities to treat brain tumors and other forms of cancer without major side effects.

As new drug compounds advance through each phase of study – moving from preclinical trials to Phase I, Phase II, Phase III and, finally, FDA approval – massive amounts of complex data must be collected and analyzed. Then, the results must be reported with meticulous detail to regulatory agencies like the US Food and Drug Administration (FDA) and to top research and educational institutions around the globe.

At NeoPharm, SAS Drug Development provides the intelligence that the company needs to manage its research data effectively and to share that research with decision makers throughout the organization. Based on a collaborative framework, the SAS solution:

- Easily integrates new research while leveraging NeoPharm's current systems and resources.
- Quickly and directly accesses data for analysis and reporting.
- Facilitates validation and programming activities that readily follow government regulations, including 21 CFR Part 11.

A single, comprehensive solution

SAS Drug Development supports regulatory submissions, intellectual property updates, study reports, professional publications and ad hoc analyses for the biopharmaceutical company. Overall, the SAS solution provides comprehensive reporting and analysis capabilities for every stage of the drug development process.

"With SAS Drug Development, everything is bundled into one product," explains Kevin Dahnert, Associate Director, who manages SAS programming at NeoPharm. "We can access data from Oracle Clinical, bring it into SAS for analysis and make different levels of information available to different people in various departments."

NeoPharm

Dahnert was originally hired to develop an in-house statistical programming department at NeoPharm. Prior to 2003, the company hired clinical research organizations to handle all data management and reporting tasks. But as NeoPharm continued to grow, and as it began to push more compounds into Phase II and III clinical trials, executives knew they would need a controlled environment for managing and validating data in compliance with FDA reporting regulations.

"SAS Drug Development makes it really easy to deploy information while still controlling who can read it versus who can update it."

Kevin Dahnert
Associate Director of Programming
NeoPharm

"Essentially, we needed a server environment that was validated and maintained, and that included versioning options, audit trails and traceability," reiterates Dahnert. "SAS Drug Development had all that, plus it was hosted and maintained outside, so we didn't need to have anyone in-house maintaining the servers and systems."

According to Dahnert, SAS met the immediate need to comply with government regulations and the solution was very easy to deploy. "Within a week of our official release to production, we were using it and converting all of our active studies to the new environment."

Validated data management

One of the ultimate – and, arguably, most important – uses for clinical study data is the investigational new drug application that pharmaceutical companies submit to the FDA. Janie Urrabazo, Assistant Director of Regulatory Submission, manages the submission process at NeoPharm.

"Our job is to take all of the information compiled by all the different departments and put it into a final document for submission to regulatory agencies," explains Urrabazo.

It's a job that is made easier by SAS Drug Development. "On the regulatory submissions side, the main reason we chose SAS Drug Development is for document version control and for the audit trails," says Urrabazo. "We want to be able to know, for every piece of data, where this information came from and who touched it."

SAS Drug Development makes that information clear for Urrabazo, for the FDA reviewers and for everyone else who touches the data.

"When I import the data, SAS Drug Development adds metadata that includes the path where that data comes from," explains Dahnert, "and that information is right there alongside the data, not outside of the environment in some other tool. It's valuable to me because it's just one application to learn and maintain. Plus, it's nice to know that I'm storing data in the same product that is used to analyze the data and pass off the deliverables."

Dahnert also likes the ability to set user permissions within the solution. "SAS Drug Development makes it really easy to deploy information while still controlling who can read it versus who can update it," he says. "SAS Drug Development gives us a way to hand off deliverables to the end users without having to use e-mail or network drives as the means of deployment."

Instead, everything remains within the SAS environment where users can access data from a user-friendly interface. "It's an environment that's easy to put workflows around," says Dahnert. "You can create a custom hierarchy of folders and permissions and keep files organized from the moment you get the data to the moment you deploy the deliverables."

Exhibit B

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Fax (919) 677-4444
www.sas.com/success

SAS | SUCCESS STORIES

PRESCRIPTION FOR GOING PAPERLESS

Daiichi Sankyo Pharma Development uses SAS® to make faster decisions about drug development

As pharmaceutical companies jostle for an edge in an ever-competitive industry, those that come out on top are the ones that have streamlined their research and development efforts for decreased drug development costs, faster time to submission, faster time to market and, thus, improved earnings.

Daiichi Sankyo Pharma Development, a New Jersey-based company, designs and conducts global experimental clinical research, coordinates global pivotal clinical trial plans, and designs and executes pivotal clinical trials in the United States.

Using SAS Drug Development as the centerpiece of a suite of hosted clinical solutions, Daiichi Sankyo Pharma Development has innovated its clinical trials processes by outsourcing the systems infrastructure of its clinical trials, allowing staff to focus on core research functions.

"Our core competency is the development of new medications, not the creation and maintenance of a clinical data management system (CDMS)," says Dr. Ron Fitzmartin, Vice President of Informatics and Knowledge Management at Daiichi Sankyo Pharma Development. "This system, with SAS Drug Development at its core, will enable Daiichi to eliminate paper-based systems – and the inevitable errors that result from the use of these systems – and help us make quicker decisions about which compounds hold the most promise."

SAS, along with the other components in the suite of leading-edge clinical trials software solutions, will fulfill Daiichi's need to capture, access, manage and use clinical trials data by providing electronic data capture (EDC), data integration, medical event auto-encoding, data visualization, and data analysis and reporting capabilities. In addition to SAS, the suite includes these hosted solutions:

- DATATRAK Aware, powered by SAS, integrates DATATRAK's EDC solution with SAS Drug Development for rapid data capture and processing.
- dsNavigator, Galt Associates' market-leading coding management solution, combines functionality for searching, navigating, batch and interactive auto-encoding, and dictionary management into a single, customizable Web-based application.
- Integrated Clinical Systems' Integrated Review and JReview perform clinical data review, reporting, multidimensional analysis, graphics and statistical modeling.

Ron Fitzmartin
Vice President, Informatics and Knowledge Management, Daiichi Sankyo Pharma Development

DAIICHI SANKYO PHARMA DEVELOPMENT

Business Issue:
Deliver integrated clinical data services that provide rapid access, review and analysis in a controlled and compliant environment.

Solution:
SAS Drug Development provides a clinical data management system so Daiichi can eliminate error-prone paper systems and make faster, more intelligent decisions.

"Changes are underway that allow data managers to spend less time on resolving data discrepancies and more time collaborating with statisticians and clinicians to facilitate rapid access to the data needed for review and decision making."
- ***Ron Fitzmartin,*** Vice President, Informatics and Knowledge Management, Daiichi Sankyo Pharma Development

READ MORE...

- Find out more about SAS Drug Development and the SAS®9 Intelligence Platform
- See how else SAS is used in life sciences
- See who else is using SAS: Customer Successes
- Visit Daiichi Sankyo Pharma Development on the Web

Delivering foresight, understanding
SAS Drug Development leverages the breakthrough capabilities of the SAS®9 Intelligence Platform to remove obstacles in sharing data and applications across organizations, delivering foresight and understanding. Available as a standalone or hosted solution with access via a secure, thin client, SAS Drug Development provides a centralized repository that allows life sciences firms to analyze their clinical research for regulatory submission and explore new market opportunities, product line extensions and safety issues – all within a controlled and secure collaborative framework designed for life sciences research companies.

This story appears in the Fourth Quarter 2005 issue of

sascom

By integrating SAS with the suite's other components, Daiichi is able to bypass the traditional CDMS, which would require a massive capital investment in IT infrastructure and a dedicated staff to install, configure and maintain the system, Fitzmartin says. And a traditional CDMS is designed to support a process for paper-based clinical trials, which Fitzmartin considers a waste of time and money.

"Changes are underway that allow data managers to spend less time on resolving data discrepancies and more time collaborating with statisticians and clinicians to facilitate rapid access to the data needed for review and decision making," Fitzmartin says. "To succeed in this transformation, the industry is eliminating transactional, paper-based processes and moving toward flexible systems that streamline the process of capturing clinical trials data and pipelining the information into a SAS repository specifically designed for data review, analysis and reporting. The scalable data repository then can be leveraged to facilitate the warehousing and mining of integrated efficacy, safety and pharmacogenomic data."

21 CFR, CDISC compliant
SAS provided a solution that is compliant with Federal Drug Administration (FDA) regulations, such as 21 CFR Part 11, which is often difficult for companies to attain. And SAS allows Daiichi to comply with data standards such as CDISC (Clinical Data Integration Standards Consortium).

"With SAS, we're going to cut out the use of transactional paper processing and go 100 percent EDC right into the SAS Drug Development repository, and then the data will be CDISC-compliant and analysis-ready," Fitzmartin says. "What's innovative about SAS and the suite of hosted solutions is that they afford us the opportunity to have best-in-breed solutions and efficiently and effectively move clinical data from an operational state into a dynamic repository."

Exhibit C

SAS Institute Inc. World Headquarters
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INC RESEARCH® LATEST ORGANIZATION TO PARTNER WITH SAS IN LIFE SCIENCE INDUSTRY

EDITORIAL CONTACTS:

Visit the SAS Press Center for more information.

Multiple partnerships formed over past year using SAS® Drug Development, SAS® Enterprise Intelligence Platform

PHILADELPHIA (June 19, 2006) – INC Research® has selected SAS® Drug Development and the SAS® Enterprise Intelligence Platform for its clinical data analysis and integration, becoming the latest of numerous scientific and IT organizations that have combined SAS technology with their own products and services to solve life science industry problems.

The sale to INC Research – a leading contract research organization (CRO) – brings to more than 25 the number of life sciences organizations using SAS Drug Development, which provides a centralized, integrated system for managing, analyzing, reporting and reviewing clinical research information.

"Even as compliance pressures continue to mount and profits continue to tighten, life science companies remain eager for a system capable of the longitudinal analysis of clinical trial data," said Chris Connor, Senior Research Analyst at IDC Health Industry Insights. "A data integration and analysis solution that can, in a cost-effective manner, simultaneously integrate clinical, operational and financial data is critical to the ability to conduct adaptive trials and enables life science companies to compete in a market growing ever more uncertain. The capabilities of SAS Drug Development, when combined with the flexibility of deploying at the customer premises or as a hosted solution, offer a compelling solution for life science companies."

One such company, INC Research manages its clients' clinical research data with its data division, DataSpectrum. Data from INC Research's Oracle Clinical implementation is pulled into SAS Drug Development for analysis and subsequent integration with other clinical trial databases.

"Our clients have a lot of data in a lot of different formats and when they go for submission, they can end up going through a crunch to get that content into the same format. Now we are able to do that work as we move through the project rather than waiting until the end and trying to bring it all together. This way is much smarter and more streamlined," said Alistair Macdonald, Vice President of INC DataSpectrum in the Americas. "SAS Drug Development gives us new capabilities to roll out with our clients, giving them a secure data environment and the ability to rapidly analyze the data and make good, informed decisions."

INC Research licenses SAS Drug Development through a hosted model, allowing its staff to focus on managing clinical trials while

SAS provides installation and implementation support through its data center. "The hosting part of the relationship – putting the power of SAS to work for our customers without them having to take on the challenge of setting up infrastructure – is fantastic," said Macdonald. "The skill set of INC Research combined with the validated infrastructure provided by SAS allows us to support customers in both rescue situations and long-term planned storage. INC Research is the only CRO with the ability to offer customers this type of service within a validated infrastructure."

Other vendors in the life science industry have seen the value of the SAS platform, expanding SAS' traditional use in clinical research to areas such as drug safety and sales/marketing. Examples include:

- Cognizant Technology Solutions, a global leader in IT services and a member of the SAS Alliance, is helping clients with their safety and signal detection challenges based on a framework called Application for Signal Processing & Intuitive Reporting (ASPIRE). "There are complexities to drug behaviors in broader populations that require a more comprehensive approach to analytics," said Nagaraja Srivatsan, Head of Life Sciences North America for Cognizant. "It was a natural conclusion to deploy ASPIRE on the SAS platform, and we see an increasing demand for it from customers. They want a unified, comprehensive software platform for making analytical decisions."
- IMS Health, the world's leading provider of market intelligence to the pharmaceutical and healthcare industries, chose SAS Enterprise BI Serverto power its Precision Sales Force™ offerings when the company's p harmaceutical clients needed to optimize their salesforce resources. The client results are impressive. "People trust SAS for its world-class analytical capability, and they trust IMS as having the most comprehensive information, as well as the best consulting assets, both locally and globally. It's a very powerful combination," said Hossam Sadek, IMS Vice President for Sales Force Effectiveness in the Americas. "Customers can pick other companies with good analytical skills or good consulting skills, but they don't have that complete continuum of information, analytics and consulting, and they're not able to do it on a global basis."

- Relsys International is the leading provider of software solutions for adverse event reporting, pharmacovigilance and risk management for the pharmaceutical industry. Rising interest in drug safety is prompting many companies to explore more advanced analytical techniques for interpreting the data in drug safety systems. "It is important that software leaders in life sciences work together to improve visibility into the behavior of pharmaceutical products," said Dave Bajaj, CEO of Relsys International. "Customers have committed to a comprehensive safety solution in our Argus suite, and they have communicated clearly that they want to see synergies with SAS leadership in clinical data mining and analytics."

"The growing use of SAS illustrates the increasing recognition by

industry organizations of SAS' platform for life sciences as a key asset," said Jason Burke, Director of U.S. Life Sciences Strategy and Solutions. "This gives SAS customers many options to derive greater insights into their research and business performance in cost effective ways, and confidence that their investment in SAS' intelligence platform is broadly supported within the industry."

Today's announcement was made at the 42nd Annual Meeting of the Drug Information Association, where SAS solutions for the life sciences as well as its continued support for industry data standards will be featured in various presentations. For more information on SAS Drug Development and SAS' proven solutions for the life sciences industry, please visit: http://www.sas.com/industry/pharma/develop.

ABOUT INC RESEARCH

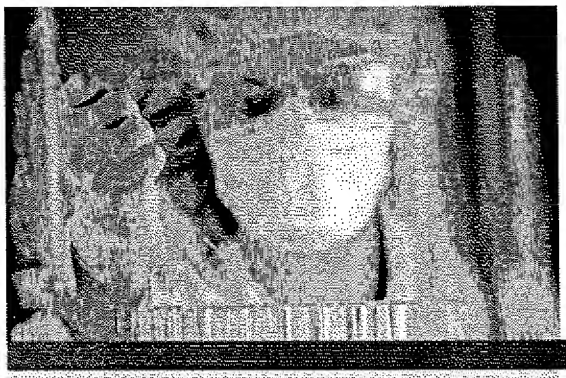
INC Research is a leading contract research organization with specialized therapeutic focus. For over two decades, the company has been dedicated to managing all aspects of global clinical development programs for pharmaceutical and biotechnology customers and tailors its full range of services, processes and technology to the unique needs of each client and their specific project requirements. Through its INC DataSpectrum division, INC Research provides a full range of data management, statistical analysis and medical writing services to support global drug development requirements for any therapeutic area. INC Research has offices in North America and Western, Eastern and Central Europe. For more information, visit www.incresearch.com.

ABOUT SAS

SAS is the leader in business intelligence software and services. Customers at 40,000 sites use SAS software to improve performance through insight into vast amounts of data, resulting in faster, more accurate business decisions; more profitable relationships with customers and suppliers; compliance with governmental regulations; research breakthroughs; and better products. Only SAS offers leading data integration, intelligence storage, advanced analytics and traditional business intelligence applications within a comprehensive enterprise intelligence platform. Since 1976, SAS has been giving customers around the world THE POWER TO KNOW®.

Back to *Recent SAS Press Releases*

Exhibit D



RX FOR GLOBAL INTELLIGENCE

Solvay Pharmaceuticals enhances worldwide drug development efforts with SAS®

Industry

Pharmaceuticals, Life Sciences

Business Issue

Expedite, globalize drug development process.

Solution

SAS® Drug Development

Benefits

Shorter time to market, decreased development costs.

Shortening drug development cycles is a primary goal of all pharmaceutical companies. But the need is compounded when companies lack sufficient means for sharing the data used in collaborative research efforts at locations spread around the globe.

Such was the case for Solvay Pharmaceuticals, a subsidiary corporation of the worldwide Solvay Group of chemical and pharmaceutical companies headquartered in Brussels, Belgium, but with test facilities in the Netherlands, United States, Germany and Japan. Using SAS Drug Development, Solvay Pharmaceuticals effectively removes geographic boundaries to make information available to all who need it, when they need it.

"The power to get to know your compound better on a global scale by using SAS Drug Development will translate into improved earnings through shorter time to market and decreased development costs," says Stefan Driessen, Solvay Pharmaceuticals' Director of Global Biometrics.

Expediting drug development

Solvay Pharmaceuticals, one of the top pharmaceutical companies in the world, focuses drug development efforts in the fields of psychiatry, gastroenterology, cardiology, male and female hormone replacement therapy, and immunology. The company invests 15 percent of sales earnings into research for new drugs.

When developing these drugs, Solvay Pharmaceuticals needs a repository to provide global, secure access to clinical information that is used by some 100 researchers around the world, working in a variety of areas, including data management, statistics, and clinical and medical review.

With SAS Drug Development, the company has found an all-in-one solution for data warehousing, analysis, reporting and exploration that transforms massive amounts of data into intelligence, which, in turn, expedites the drug development process.

Solvay Pharmaceuticals collects a huge amount of information during clinical trials, explains Rick Miller, Director of Clinical Information Management for Solvay Pharmaceuticals. The data must be stored electronically while remaining easily accessible. Meanwhile, the company has to ensure it complies with stringent regulations placed on electronic data systems by the US Food and Drug Administration (FDA). And Solvay Pharmaceuticals must efficiently deal with data coming in from other companies around the world, including outsourced clinical trials.

Solvay Pharmaceuticals

"Whether we're doing development in Europe or in the US, we need to be able to combine and share data – and learn from it – so that we can submit it for regulatory approval," Miller says. "SAS gives us the ability to be a truly global organization."

THE POWER TO KNOW.

"The power to get to know your compound better by using SAS will translate into improved earnings through shorter time to market and decreased development costs."

Stefan Driessen
Director of Global Biometrics
Solvay Pharmaceuticals

Rendering time zones irrelevant

Not only does Solvay Pharmaceuticals bring together information from its own research facilities in Europe and America, but it also works with outside development companies from around the world. Solvay Pharmaceuticals must bring together common technical documents from clinical trials around the world and analyze the data regularly to make sure, for example, that no safety concerns exist. And, at the end of a study, Solvay Pharmaceuticals needs to test the product's efficacy.

"The transfer of data back and forth, especially when studies are ongoing, is critical to making sure we get a feel early as to whether the drug is safe," Miller explains.

The sooner a drug is determined not to be a good prospect, for example, the more the company can save in terms of research costs. "And we want to get it approved in the United States as well as in Europe, Asia and all over the world," Miller says. "So we're looking at clinical data that's coming in regularly, and we're sharing that data with each other around the world."

With SAS, Solvay Pharmaceuticals researchers around the world can query and explore the same data without the drag of time differences that once slowed the sharing of knowledge and the discovery of intelligence. "Operating on a global scale can be difficult because people need to look at the same information – often at the same time," Driessen says. "It used to take months and months to collect data from around the world, and months and months to come up with usable answers to our queries. But now, using SAS, we can do all that in a week."

Eventually, Driessen and Miller will use SAS to combine drug studies "on the fly" as they are completed. That way, Solvay Pharmaceuticals will have an integrated database ready to offer plenty of insight into future studies. "You can run trials, look at the data, understand what your compound is doing and be able to make better decisions," Miller explains. "And that will make it easier to manage our portfolio of compounds and will help us get them to market faster."